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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0840; FRL-9933-27]

Acibenzolar-S-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acibenzolar-S-methyl in or on fruit, citrus, group 10-10 and fruit, pome, group 11-10. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0840, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0840 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0840, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8269) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC. The petition requested that 40 CFR 180.561 be amended by establishing tolerances for residues of the fungicide, acibenzolar-*S*-methyl, in or on pome fruit, crop group 11-10 at 0.03 parts per million (ppm) and citrus fruit, crop group 10-10 at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance for residues of acibenzolar-*S*-methyl in or on fruit, citrus, group 10-10 at 0.02 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acibenzolar-*S*-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acibenzolar-*S*-methyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In subchronic and chronic oral studies in rats, dogs and mice, signs of mild regenerative hemolytic anemia were consistently observed in all three species. These signs frequently included decreased erythrocyte counts, decreased hemoglobin, decreased hematocrit, increased reticulocyte counts, increased hemosiderosis in the spleen, liver and/or bone marrow, extramedullary hematopoiesis in the spleen, and increased spleen weights in both males and females. A compensatory response (increased erythrocyte production) regularly followed the initial anemia. Additional toxic effects observed in these same studies included decreases in body weight, body weight gain and/or food consumption. No other significant treatment-related effects of toxicological concern were observed in these subchronic and chronic oral studies. In a 28-day dermal study in rats, no systemic or dermal effects were observed at dose levels up to 1,000 milligram (mg)/kilogram (kg)/day, the limit dose. No neurotoxic effects were observed at any dose in a subchronic neurotoxicity study in rats.

Treatment-related developmental malformations, anomalies and variations were observed in a developmental toxicity study in rats at or below the no observable adverse effect level (NOAEL) for maternal toxicity. At the highest dose tested in this study (400 mg/kg/day), both maternal toxicity (hemorrhagic perineal discharge) and considerable developmental toxicity (including total litter resorptions, fetal malformations, anomalies and variations) were observed. The fetal malformations noted at this dose included treatment-related effects on nervous system tissues (hydrocephaly, craniorachisis and anophthalmia/ microphthalmia). At the next lower dose tested (200 mg/kg/day), treatment-related visceral malformations and skeletal variations were demonstrated in the absence of significant maternal toxicity. A similar increased sensitivity of fetuses or pups (as compared to adults) was not observed in a developmental toxicity study in rabbits or in 2-generation and 1-generation (range-finding) studies in rats. In a dermal developmental toxicity study in rats, no maternal or developmental toxicity was observed at dose levels up to 500 mg/kg/day, the highest dose tested.

In a battery of mutagenicity studies, results were negative in all studies except in an *in vitro* chromosome aberration study in Chinese hamster ovary (CHO) cells, in which there was evidence of a clastogenic response in the absence of S-9 activation.

In a 2-year chronic toxicity/carcinogenicity study in rats and an 18-month carcinogenicity study in mice, acibenzolar-S-methyl was negative for carcinogenicity when administered at dose levels adequate for the testing of carcinogenic potential.

Acibenzolar-S-methyl showed no significant toxicity in a battery of acute toxicity tests (Toxicity Category III or IV in all tests). Considerable skin sensitizing (contact allergenic) potential was demonstrated in a dermal sensitization study in guinea pigs for the technical grade material. The end-use product did not show dermal sensitization in guinea pigs.

Specific information on the studies received and the nature of the adverse effects caused by acibenzolar-*S*-methyl as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled "Acibenzolar-*S*-Methyl. A Human Health Risk Assessment to support Section 3 Use of Acibenzolar-*S*-Methyl Uses on Citrus Crop Group 10-10, and Pome Crop Group 11-10 at pages 39-44 in docket ID number EPA-HQ-OPP-2014-0840.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for acibenzolar-*S*-methyl used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Acibenzolar-*S*-Methyl for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-49 years old and children 1-12 years old)	NOAEL = 8.2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.082 mg/kg/day aPAD = 0.082 mg/kg/day	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal NOAEL = 326.2 mg/kg/day (highest dose tested); no effects observed in maternal animals
Chronic Dietary (Females 13-49 years old and children 1-12 years old)	NOAEL = 8.2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.082 mg/kg/day cPAD = 0.082 mg/kg/day	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal NOAEL = 326.2 mg/kg/day (highest dose tested); no effects observed in maternal animals
Chronic Dietary (Males 12+ yrs. and Females 50+ yrs.)	NOAEL = 25 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.25 mg/kg/day cPAD = 0.25 mg/kg/day	Chronic Toxicity - Dog; Co-critical; Chronic/Cancer - Rat and Mouse, Reproduction Toxicity - Rat LOAEL = 105 mg/kg/day based on hemolytic anemia with compensatory response.

Incidental Oral	NOAEL = 8.2 mg/kg/day UF _A = 10x UF _H = 10x	Occupational LOC for MOE = 100	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal NOAEL = 326.2 mg/kg/day (highest dose tested); no effects observed in maternal animals
Cancer (all routes)	EPA has determined that acibenzolar-S-methyl is not likely to be a human carcinogen.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acibenzolar-S-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing acibenzolar-S-methyl tolerances in 40 CFR 180.561. EPA assessed dietary exposures from acibenzolar-S-methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for acibenzolar-S-methyl for females 13-49 years old and children 1-12 years old. No acute endpoint was identified for the general population/adults. In estimating acute dietary exposure,

EPA used food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) 2003-2008. A probabilistic assessment was performed for the acute analysis. Foods were classified as blended, partially blended, or non-blended. The acute analysis assumed a distribution of residues based on field-trial data for non-blended and partially blended commodities. For blended commodities, the mean field-trial values were used as a point estimate. A value of $\frac{1}{2}$ level of quantification (LOQ) was used for samples that contained less than LOQ residues. Time-limited tolerance values were used (0.05 ppm) for the Experimental Use Permit (EUP) commodities, i.e., apple, pear, and grapefruit. Section 3 tolerance-level residues were used for all other citrus and pome fruit commodities. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for apple juice, cranberry juice, dried apples, dried pears, dried onion, dried banana, dried plantain, and dried tomato. Empirical processing factors were used for citrus juice (1.0), tomato paste (7.1), tomato puree (2.9), and tomato juice (1.0). Residues of acibenzolar-S-methyl did not concentrate in citrus juice or oil. The acute analysis used available maximum percent crop treated (MPCT) estimates and assumed 100 PCT for commodities for which no PCT data were available. Based on the lettuce metabolism data, a factor of 1.5X was applied to estimates of acibenzolar-S-methyl residues to account for all of the residues of concern for dietary risk (including CGA-210007, CGA-323060 and CGA-324041).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA NHANES/WEIA 2003 – 2008. A conservative chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. In the chronic dietary exposure analysis, tolerance-level residues were used and 100% CT was assumed for all commodities. Temporary tolerance values were used for apple, pear, and grapefruit, since they are higher than the new section 3 tolerances, and do not expire

until 12/31/2015. Section 3 tolerance levels are used for all other crop group 10-10, and pome crop group 11-10 commodities. DEEM default processing factors were used for apple juice, dried apples, cranberry juice, dried apple, dried pears, dried onion, dried banana, dried plantain, and dried tomato. A processing factor was not used for tomato paste because a separate tolerance has been established for this processed commodity. In the submitted tomato processing study, processing factors of 1.0 and 2.9 were reported for tomato juice and tomato puree, respectively. These processing factors were used in the dietary exposure assessment. Residues of acibenzolar-*S*-methyl did not concentrate in citrus juice or oil based on a processing study, so a processing factor of 1.0 was used. A factor of 1.5X was applied to estimates of acibenzolar-*S*-methyl residues to account for all of the residues of concern for dietary risk (including CGA-210007, CGA-323060 and CGA-324041).

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that acibenzolar-*S*-methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute dietary analysis, EPA estimated PCT for the following crops for which uses of acibenzolar-S-methyl are currently registered based on available MPCT estimates: Broccoli: 10%; cabbage: 2.5%; cauliflower: 10%; lettuce: 10%; peppers: 10%; spinach: 50%; and tomatoes: 10%.

In the chronic dietary exposure analysis, 100 % CT was assumed for all commodities.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be

reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for acibenzolar-*S*-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acibenzolar-*S*-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Surface water estimated drinking water concentrations (EDWCs) were generated for the total residues of acibenzolar and CGA 210007 using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model for all proposed uses. Exposure in ground water due to leaching was assessed with the Pesticide Root Zone Model Ground Water (PRZM-GW). The EDWCs of acibenzolar-*S*-methyl for acute exposures are estimated to be 47.19 microgram per liter ($\mu\text{g/L}$) for surface water (citrus) and 13.33 $\mu\text{g/L}$ for ground water. For chronic exposures (non-cancer) assessments the EDWC is 13.33 $\mu\text{g/L}$ for surface water (apple).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 47.19 $\mu\text{g/L}$ was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.33 $\mu\text{g/L}$ was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acibenzolar-S-methyl is not being registered for any specific use patterns that would result in residential exposure in this action. However, a revised post-application residential exposure assessment was conducted to update the residential exposures based on the 2012 revised Residential SOPs.

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with acibenzolar-S-methyl. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios: Adult, 11 to <16 years old, and 6 to <11 years old dermal exposure from playing golf on treated golf courses (short-term dermal exposure).

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found acibenzolar-S-methyl to share a common mechanism of toxicity with any other substances, and acibenzolar-S-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acibenzolar-S-methyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the rat developmental toxicity study, treatment-related visceral malformations and skeletal variations were observed in fetuses at 200 mg/kg/day, the NOAEL for maternal toxicity. In the developmental neurotoxicity study, offspring toxicity was observed at 82 mg/kg/day while no maternal toxicity was observed at 326 mg/kg/day, the highest dose tested. Additional developmental toxicity studies in rats and rabbits and reproduction studies in rats provided no indication of increased susceptibility of rat or rabbit fetuses or neonates compared to adult animals.

3. *Conclusion.* The FQPA factor for increased susceptibility to infants and children is reduced to 1x based on the following considerations.

i. The toxicology database for acibenzolar-S-methyl is complete and adequate for assessing increased susceptibility under FQPA. The pre- and postnatal toxicity database for acibenzolar-S-methyl includes developmental toxicity studies in rats and rabbits, a developmental neurotoxicity study (DNT) study in rats, and a 2-generation reproduction toxicity study in rats.

ii. There is some evidence of potential neurotoxicity in a developmental neurotoxicity study. Although there were no treatment-related offspring effects seen on survival, clinical

signs, functional observational battery (FOB), developmental land marks, brain weights or neuropathology, significant morphometric changes (decreased thickness of the molecular layer of the cerebellum) were observed in male offspring on postnatal date (PND) 63 at 82 mg/kg/day. At the high dose, treatment-related offspring effects included decreased body weights, increased auditory startle response and increased thickness in the corpus callosum in females. No effects were observed in maternal animals at the highest dose tested. However, in a subchronic neurotoxicity study in rats, no compound-related effects were observed in the FOB, motor activity, gross pathology or neuropathology at the highest doses (575/628 mg/kg/day, male/female) tested.

iii. Based on the developmental toxicity in rats and the developmental neurotoxicity studies in rats, there is concern for increased qualitative and/or quantitative susceptibility following in utero exposure to acibenzolar-*S*-methyl. However, the degree of concern for the increased susceptibility seen in these studies is low, as there are no residual uncertainties with regard to pre- and/or postnatal toxicity since (1) NOAELs and LOAELs have been identified for all effects of concern, (2) a clear dose response has been well defined, and (3) the points of departure selected for risk assessment are protective of the fetal/offspring effects.

iv. There are no residual uncertainties identified in the exposure databases. The refined acute dietary assessment utilizes maximum percent crop treated estimates but is still considered conservative, since it is based on field trial data treated at the shortest preharvest interval and maximum use rate. The chronic dietary and residential risk assessments are also conservative. These assessments will not underestimate dietary and/or non-dietary residential exposure to acibenzolar-*S*-methyl. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acibenzolar-*S*-methyl in drinking

water. EPA used similarly conservative assumptions to assess post-application exposure. These assessments will not underestimate the exposure and risks posed by acibenzolar-*S*-methyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acibenzolar-*S*-methyl will occupy 33% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acibenzolar-*S*-methyl from food and water will utilize 13% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There is potential short-term exposure to acibenzolar-*S*-methyl via the dietary pathway and the residential pathway (golfing on treated golf courses). Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,300 for children 6 to <11 years old. Because EPA's level of concern for acibenzolar-*S*-methyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since the short- and intermediate-term PODs are the same and short-term exposure estimates are greater than their intermediate-term counterparts, the short-term aggregate risk assessment is protective of the intermediate-term aggregate exposure.

5. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk was not calculated because acibenzolar-S-methyl was classified as “not likely to be carcinogenic to humans”.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acibenzolar-S-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

HPLC/UV Method AG-617A is available for tolerance enforcement. The method consists of an initial hydrolysis with NaOH to convert acibenzolar-S-methyl to CGA-210007 followed by methanol extraction. Residues are then diluted with HCl and purified by a series of solid-phase extraction steps. Prior to HPLC/UV analysis, residues are partitioned into ethyl acetate, dried down, and re-dissolved in phosphoric acid. This method has a LOQ of 0.02 ppm. The method includes optional detection via HPLC/MS, giving a means of residue confirmation.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acibenzolar-*S*-methyl.

C. Revisions to Petitioned-For Tolerances

The tolerance level for fruit, citrus, group 10-10 (0.02 ppm) is being set at the LOQ of the enforcement method which is higher than the petitioned-for tolerance (0.01 ppm). The names of the crop groups for citrus and pome fruit are being corrected to fruit, citrus, group 10-10 and fruit, pome, group 11-10.

V. Conclusion

Therefore, tolerances are established for residues of acibenzolar-*S*-methyl, fungicide, in or on fruit, citrus, group 10-10 at 0.02 ppm and fruit, pome, group 11-10 at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these

types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255,

August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 4, 2015.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.561, is amended by adding alphabetically the entries for “Fruit, citrus, group”, and “Fruit, pome, group” to the table in paragraph (a)(1) to read as follows:

§ 180.561 Acibenzolar-*S*-methyl; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* * *
Fruit, citrus, group 10-10	0.02
Fruit, pome, group 11-10	0.03
* * *	* * *

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